

REMARKS

A. Status of the Claims

Claims 5, 6, 7, and 8 have been amended without prejudice. Support for the amendments can be found throughout the specification, e.g., Example 5 as well as on page 3, line 10 to page 4, line 24;

Claims 9-12 have been canceled without prejudice. Claims 1-4 were previously canceled without prejudice.

New Claims 13-20 have been added pursuant to an interview with the Examiner as discussed below. Support for the new claims can be found throughout the specification, e.g., on page 4, lines 20-24.

Accordingly, Claims 5-8 and 13-20 are currently pending in the application.

Applicants respectfully submit that no new matter was added by virtue of this amendment. Check No. 11416 has been included herewith to cover the fees for additional independent claims pursuant to 37 CFR Section 1.16 (h) as well as Check No. 11415 for a one month extension of time pursuant to 37 CFR Section 1.17 (a)(1).

A. Statement of Interview pursuant to 37 CFR 1.133

In accordance with the provisions of 37 CFR 1.133, Applicants herein make of record the substance of the interview conducted on December 11, 2007, between Applicants' attorneys, Oleg Ioselevich, R. Cole Harrington and Examiner David H. Kruse.

During the interview, claims 5 through 12 (currently pending in the case as of the interview date) and U.S. Patent No. 6,417,428 to Thomashow et al. were discussed in view of the rejections made in the Office Action mailed on September 20, 2007. Applicants discussed with the Examiner the further amendment of claims 5-8 to incorporate the Markush listing of promoters set forth in then pending claims 9-12 (now canceled) as well as the addition of several new claims as discussed hereinbelow for the purpose of reconsideration or, alternatively, for placing them in better condition for consideration on appeal.

In the aforementioned interview, the Examiner *expressed a willingness* to reconsider, after final, *any amended claims that were limited specifically to the rd29a promoter* provided that *Applicants were willing to demonstrate by way of a rule 1.132 declaration that they were the first to isolate and characterize the rd29a gene* (see Yamaguchi-Shinizaki and Shinozaki, Plant Physiol. 101: 1119-1120 (1993) as set forth in the cited reference, US Patent 6,417,428 to Thomashow, et al. (see column 47, lines 63-67 and column 20, lines 38-67). Applicants hereby request subsequent entry of such declaration by the Examiner once it is available and can be transmitted under a supplemental response that shall be forthcoming.

Additionally, in acknowledgment of rule 1.116(b)(3), Applicants respectfully submit that earlier presentation of the amended claims was not possible as Applicants' insight to the Examiner's rejections had not yet been clarified prior to the interview. To that end, Applicants have provided new claims 13-16, entry and favorable consideration of which is hereby earnestly solicited.

Applicants have also *amended* claims 5-8 to recite a Markush grouping of 5 promoters that include rd29a as well as 4 more promoters that behave similarly to rd29a in that they all have a surprisingly increased binding affinity relative to other promoters and unexpectedly impart to a transgenic plant a notable resistance to dwarfism and result in an improved phenotypic tolerance to environmental stresses such as cold. Moreover, Applicants have also added new claims 17-20 that recite that same Markush grouping but additionally recite *improved tolerance to dehydration, low temperature or salt, as compared to a wild type plant, and is free from dwarfing*, something that is not taught or suggested by the Thomashow patent as will be further discussed below.

As such, Applicants have respectfully retained amended claims 5-8 and added new claims 17-20 in the instant case for favorable reconsideration by the Examiner, or alternatively, to place the case in more favorable light on appeal, entry of which is earnestly solicited.

C. Rejections Under 102/103

In the outstanding Office Action of September 20, 2007, the Examiner has indicated that claims 5-8 (as amended by Applicants in their response of June 26, 2007) and new claims 9-12 (as first presented by Applicants, also in their response of June 26,

2007) are rejected under 35 U.S.C. § 102(e) as being anticipated by, or, in the alternative, obvious over 35 U.S.C. § 103(a), over U.S. Patent No. 6,417,428 (Thomashow et al.).

In particular, the Examiner has stated at page 3 of the instant office action that the sequences as claimed by Applicants and as disclosed by Thomashow are basically identical and further that:

Applicants argue that at the time of filing of this application, it was not known in the art what kind of promoters should be used for high level and stable expression of artificially introduced genes only when the plant is subject to the stress. *Applicants argue that the inventors were the first to find and demonstrate that, e.g., the self amplification mechanism, i.e., the use of a promoter comprising DRE region as presently claimed, is useful for producing stress resistant plants* (page 5, 1st paragraph of the Remarks). This argument is not found to be persuasive. *There is no requirement that a person of ordinary-skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter "is in fact inherent in the prior art reference.* See *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) which teaches, "[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention." [*italics, ours for reference thereto*]

Applicants respectfully disagree with the Examiner's position as to inherent anticipation. Applicants' claimed invention, as currently amended in claims 5-8 and as newly presented in claims 17-20 (as well as that set forth in new claims 13-16) recites either a single promoter (claims 13-16) or a group of promoters (claims 5-8 and 17-20) that is/are distinctly yet unexpectedly different than the laundry list of promoters recited in Thomashow. Applicants respectfully maintain that it is the uniqueness of the 5 claimed promoters that places them in their own category as to functionality and effectiveness and this grouping that includes the five named promoters or there membership of that unique group is simply nowhere disclosed or taught in any manner by Thomashow.

While the Examiner has put forth that there is no requirement that one ... *would have recognized the inherent disclosure at the time of invention, but only that the subject matter "is in fact inherent in the prior art reference"*...the fact remains that this grouping of promoters and/or the individual membership thereof as set forth in Applicants' claims is a unique and distinct feature of Applicants' claimed invention that is simply not present anywhere in the text or figures of the Thomashow reference. Moreover, there is clearly no disclosure of dwarf resistant plant transformed by a DNA...operably linked downstream of a stress responsive promoter comprising DRE region(s) wherein the promoter is selected from a group of unique promoters having unexpectedly improved binding affinities resulting in a

surprisingly improved response to environmental stresses and the resistance of dwarfism. As such, Applicant respectfully submits that the reference does not anticipate or render obvious the present invention and respectfully request that the Examiner withdraw the aforementioned rejections as based upon Thomashow.

The Examiner has also stated at page 4 of the instant office action that:

Applicants argue that Thomashow et al. describe nothing about the stress responsive promoter comprising DRE region(s) as recited in the present claims. Applicants argue that, instead, Thomashow et al. describe a "tissue specific promoter" that is used to alter COR gene expression in tissues that are highly sensitive to stress and "a promoter that turns on at warmer temperature than the temperature at which the plant normally exhibits cold tolerance (See page 29 of Thomashow et al.). Applicants argue that the latter promoter means a promoter that is similar to a constitutive promoter, because this promoter can induce the gene expressions at warmer temperature than the temperature at which the plant normally exhibits cold tolerance (page 5, 5th paragraph of the Remarks). These arguments are not found to be persuasive. *The test for adequacy of a prior art disclosure to anticipate or render claims obvious is not the same test as that for adequacy of a patent application. [italics, ours for reference thereto]*

Applicants respectfully point out that the Examiner appears to have taken their aforementioned argument out of context. The reference to Thomashow's "tissue specific promoter" that is used to alter COR gene expression was mentioned to highlight Applicants' unique deployment of the specialized promoters as grouped together and claimed by Applicant which was not done or mentioned by Thomashow. The grouping of the 5 specialized promoters as well as their membership in such group is not disclosed in Thomashow. The fact that the Thomashow approach results in a less favorable result is mentioned by Applicants as a classic example of secondary indicia of nonobviousness, namely the recognition of an existing problem and a need for improvement.

The fact that Thomashow approach renders a less favorable result than Applicants' is an additional consideration that Applicants mention to illustrate that their invention is not obvious or it would have been put forth by Thomashow, and moreover that anticipation cannot hold because it no way does Thomashow disclose such a grouping based on the improved promoter performance that is characteristic of such group.

By way of argument and not admission, if all the elements of Applicants' invention are present in Thomashow and the claimed invention is anticipated and/or obvious as Examiner puts forth, it would have been expressly disclosed since the overall subject matter of Thomashow is clearly conducive to such a rendering as the Thomashow

inventors were obviously attempting to create the best environmental stress resistant plant known to them at the time.

Respectfully, Applicants are not, as suggested by the Examiner, arguing that the inadequacy of Thomashow's approach renders the reference moot as to an argument in favor of anticipation and/or obviousness, but rather the inadequacy further highlights the lack of disclosure in Thomashow as to the claimed features of Applicants' invention, namely Applicants' unique grouping of the five claimed promoters and the membership thereof that is simply not disclosed or taught in any manner by Thomashow. Accordingly, Applicants respectfully request that the Examiner withdraw the aforementioned rejections as based upon Thomashow.

The Examiner has also stated at page 5 of the instant office action that:

Applicants argue that Thomashow et al. states that "a strong constitutive promoter could be used to cause increased levels of COR gene expression in both nonstress and stressed plants which in turn, results in enhanced freezing and dehydration tolerance." Applicants argue that Thomashow et al. provide only a transgenic plant transformed with CBF 1 gene under the control of the strong constitutive promoter: cauliflower mosaic virus (CaMV) 35S promoter (See page 45, last paragraph of Thomashow et al.) as working examples of transgenic plants, however as discussed above, when a promoter such as CaMV35S which induces the expression of a plurality of genes is introduced into a host plant, the genes are activated at the same time. Applicants argue that as a result, the energy of the host plant is directed to production of the products of these genes and intracellular metabolism of such gene products, which often brings about delay in the growth of the host plant or dwarfing of the plant (See Example 4 of the present invention). Applicants argue that Thomashow et al. do not teach or suggest part a protein or a DNA " ... operably linked downstream of a stress responsive promoter comprising DRE region(s)" as recited in the present claims. Arguments on page 6, 1st-3rd paragraph of the Remarks. These arguments are not found to be persuasive. *There is no requirement that Thomashow et al had to reduce to practice a structure disclosed in the patent.* [italics, ours for reference thereto]

Applicants respectfully point out that similar to the aforementioned issue, the Examiner appears to have taken their instant argument out of context. The reference to Thomashow's use of a CBF 1 gene in conjunction with a CasMV35S promoter that results in the expression of plurality of genes being activated at the same time was mentioned to highlight Applicants' unique deployment of the specialized promoters as set forth in Applicants' claims that indeed was not done, disclosed or mentioned by Thomashow. Accordingly, the more favorable expression of proteins as accomplished by Applicants' invention sets forth another classic example of secondary indicia of nonobviousness.

The fact that Thomashow disclosure does not reduce to practice Applicants' invention is indeed a true statement. Applicants respectfully point this out because it

provides even greater weight to the argument that that their invention is not anticipated or obvious or it would have been put forth by Thomashow *since the Thomashow inventors were attempting to produce the best stress resistant plant known to them at the time*. By way of argument and not admission, if all the elements of Applicants' invention are present in Thomashow and the claimed invention is anticipated and/or obvious as Examiner puts forth, it would have been expressly disclosed since the subject matter of Thomashow is clearly conducive to such a rendering.

Respectfully, Applicants are not, as suggested by the Examiner, arguing that the inadequacy of Thomashow's approach renders the reference moot as to an argument in favor of anticipation and/or obviousness, but rather the inadequacy further highlights the lack of disclosure in Thomashow as to the claimed features of Applicants' invention, namely that Applicants' grouping of the five individual promoters set forth in Applicants' claims that is simply not disclosed or taught in any manner by Thomashow. Accordingly, Applicants respectfully request that the Examiner withdraw the aforementioned rejections as based upon Thomashow.

Lastly, the Examiner has stated on page 6 of the outstanding action that:

Applicants argue that Thomashow et al. *teach away from the use of stress responsive promoter comprising an ORE region* (e.g., to which said OREB 1 B protein can bind) as presently claimed (page 6, 5th paragraph of the Remarks). This argument is not found to be persuasive. Thomashow et al teach "In each of the above embodiments, expression of the recombinant copy of the regulatory gene may be under the control of the promoter. The promoter may increase the level at which the regulatory gene is expressed, express the regulatory gene without being induced by an environmental stress or express the regulatory gene in response to a different form or degree of environmental stress that would otherwise be needed to induce expression of the regulatory gene. For example...[emphasis ours]"

In response to the foregoing, Applicants point out that Applicants' claimed invention, as currently amended in claims 5-8 and as newly presented in claims 17-20 (as well as that set forth in new claims 13-16) recites either a single promoter (claims 13-16) or a group of promoters (claims 5-8 and 17-20) that is/are distinctly yet unexpectedly different than the laundry list of promoters recited in Thomashow. Applicants respectfully maintain that it is the uniqueness of the 5 promoters grouped together in Applicants' claims that places them in their own category as to functionality and effectiveness and this grouping is simply nowhere disclosed or taught in any manner by Thomashow.

Additionally, Applicants hereby respectfully maintain for the record their position that Thomashow et al. teach away the use of stress responsive promoter comprising a DRE region to which said DREB1B protein can bind. It is Applicants' use of the stress-responsive promoter enables DREB1B gene to amplify itself in response to environmental stress (self-amplification). As a result of high level and stable expression of DREB1B gene in a short period of time, the transgenic plant acquires stress resistance without dwarfing. At the time of filing of this application, it was not known what kind of promoters should be used for high level and stable expression of artificially introduced genes that activate only when the plant is subject to the stress. Applicants found and demonstrated, for the first time in the world, that the self-amplification mechanism, i.e. the use of a promoter comprising DRE region, is useful for producing excellent stress resistant plants.

As described above, when a promoter such as CaMV35S which induces the expression of a plurality of genes is introduced into a host plant, the genes are activated at the same time. As a result, the energy of the host plant is directed to production of the products of these genes and intracellular metabolism of such gene products, which often brings about delay in the growth of the host plant or dwarfing of the plant. (see Example 4 of the present invention).

The rd29A promoter is mainly regulated via DRE system rather than a plant hormone "ABA" system. rd29A promoter contains plural DRE regions (four DRE regions) and these DRE regions are very effective DREs to which transcription factor DREB can strongly bind. Importantly, rd29B promoter is mainly regulated via a plant hormone "ABA" system rather than DRE system. rd29B promoter has a DRE region, but this DRE is ineffective DRE to which transcription factor DREB can bind very weakly.

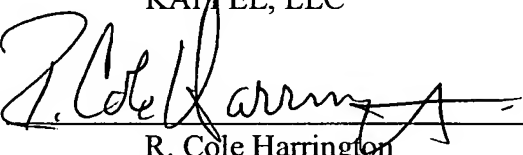
DREs have a core sequence "CCGAC." However, there are different DREs with different sequences. The best DRE has the sequence of "A/GCCGACNT." rd29A promoter has the best DRE, while rd29B promoter has other DRE. The transcription factor DREB can strongly bind to the former DRE, but very weakly bind to the latter one. Therefore, the latter DRE cannot induce the expression of the genes located downstream of the DRE.

The present inventors recognized that the stress-responsive promoter did not cause the delay in growth or dwarfing of the plant, while the constitutive promoter, 35S promoter, caused the delay in growth or dwarfing of the plant. In addition, the present inventors fully recognized the mechanism in which DREB genes enhanced the stress-resistance in a plant via stress-responsive promoter. Therefore, they did not claim the use of rd29B promoter.

Thomashow et al. describe nothing about the stress-responsive promoter in the manner and to the degree present in the instant application nor did they have any idea about the merits of the stress-responsive promoter or they would have set forth a specialized grouping of the best promoters as did the present Applicants. Rather, Thomashow et al merely set forth a laundry list of all the promoters known as of the filing date of their application.

Accordingly, for the foregoing reasons, Applicants respectfully request reconsideration of the present claims, as amended, and withdrawal of the rejections over the Thomashow et al., the action of which is earnestly solicited.

Respectfully Submitted,
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